Date of Hearing: June 23, 2026

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
SB 1224 (Jones) – As Amended June 11, 2026

SENATE VOTE: Not relevant.

SUBJECT: The California Emerging Therapies Research Partnership Act.

SUMMARY: Establishes the California Emerging Therapies Research Partnership Fund (Fund) to be administered by the State Department of Health Care Services (DHCS) and the Department of Veterans Affairs (CalVet), to, among other things, issue grants to a University of California (UC) campus to serve as an anchor institution for a federally registered emerging therapies clinical trial. Defines "emerging therapies" to mean psilocybin, ibogaine, 3,4-methylenedioxymethamphetamine (MDMA), dimethyltryptamine, and ketamine when used in the context of a federally registered clinical trial. Requires the California Health and Human Services Agency (CalHHS) in coordination with DHCS, CalVet, and the office of the President of UC (UCOP), to submit a complete application for partnership designation to the federal Advanced Research Projects Agency for Health (ARPA-H). Requires DHCS, within 90 days of receiving ARPA-H partnership designation, to execute a data-sharing memorandum of understanding (MOU) with specified federal agencies to establish protocols for the sharing of deidentified, aggregated clinical trial outcome data. Requires CalVet to convene the California Veteran Emerging Therapies Research Advisory Council (Council), with specified membership, to, among other things, serve as the primary advisory body to DHCS, CalVet, and CalHHS on matters relating to emerging therapies research for veterans and other priority populations. Requires the Council to submit a needs assessment to CalVet, CalHHS, and the Legislature. Specifically, **this bill**:

1) Requires DHCS to request that UC participate in the activities described in this bill.

2) Establishes the Fund as a special deposit fund within the State Treasury.

3) Continuously appropriates moneys in the Fund to DHCS and CalVet without regard to fiscal year for the purposes of this bill.

4) States that moneys in the Fund are not General Fund (GF) revenues and are not subject to appropriation in the annual Budget Act.

5) Permits the Fund to receive any of the following:

   a) Federal grants, awards, and partnership payments received pursuant to an ARPA-H partnership designation or a substantially similar federal emerging therapies research program;

   b) Federal grants or research awards received from the United States Department of Veterans Affairs (USVA), the National Institutes of Health, or another federal agency in connection with emerging therapies clinical research; and,

c) Gifts, bequests, and philanthropic contributions made to the state for emerging therapies research purposes, upon appropriation by the Legislature.

6) Prohibits GF moneys from being deposited into the Fund. States the existence of the Fund does not constitute a commitment of state funds or a GF obligation of any kind.

7) Requires moneys in the Fund to be used only for the following purposes:

   a) Issue grants to a UC campus to serve as an anchor institution for a federally registered emerging therapies clinical trial, including direct costs of trial operations, patient recruitment infrastructure, and data reporting;

   b) Costs incurred by DHCS in executing and maintaining data-sharing MOUs with the United States Department of Health and Human Services (HHS), the United States Food and Drug Administration (FDA), and the USVA;

   c) Costs incurred by the CalVet in convening and staffing the Council convened pursuant to 19) below; and,

   d) Administrative costs of DHCS and UCOP in implementing this bill, not to exceed 5% of funds received in a fiscal year.

8) Prohibits moneys in the Fund from being used to do any of the following:

   a) Purchase, distribute, or administer a controlled substance;

   b) Establish a therapeutic access program; or,

   c) Support an activity that is not specifically authorized in this bill.

9) Requires CalHHS to, no later than 60 days after the operative date of this bill, and in coordination with DHCS, CalVet, and UCOP, to submit a complete application for partnership designation pursuant to the April 18, 2026, executive order or any substantially equivalent federal program to ARPA-H for the purpose of making California eligible to receive federal emerging therapies research moneys.

10) Requires the application to include, at minimum, all of the following:

   a) The UC System Research Readiness Certification submitted by the UCOP pursuant to 15) below;

   b) A description of the Fund and its legal authority to receive federal awards;

   c) A description of the Council convened pursuant to 18) below;

   d) A data-sharing framework demonstrating California's capacity to share deidentified clinical trial outcome data with federal partner agencies in compliance with applicable federal privacy law; and,

   e) Within 90 days of partnership designation, a proposed schedule for execution of data-sharing MOUs with HHS, the FDA, and USVA.

11) Requires CalHHS to amend or supplement California's application, as necessary, to maintain eligibility and notify the Legislature within 30 days of a material change to the federal program requirements if ARPA-H or a substantially similar federal program issues supplemental guidance, an amendment to application requirements, or an alternative funding vehicle after the effective date of this bill.

12) Permits the Joint Legislative Budget Committee, the Assembly Committee on Health, the Senate Committee on Health, the Assembly Committee on Military and Veterans Affairs, and the Senate Committee on Military and Veterans Affairs to request an interim briefing from CalHHS on the status of the ARPA-H partnership application at any time following its submission. Requires CalHHS to respond to the request within 30 days.

13) Requires DHCS to execute a data-sharing MOU with HHS, the FDA, and USVA within 90 days of receiving ARPA-H partnership designation. Requires each MOU to establish protocols for the sharing of deidentified, aggregated clinical trial outcome data generated by a UC anchor institution with the relevant federal agency for the purposes of advancing emerging therapies research and supporting federal regulatory review.

14) Prohibits an MOU executed pursuant to this bill from requiring the disclosure of personally identifiable patient information or individually identifiable health information in a manner inconsistent with the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA, see 11) and 12) of Existing Law below) or the Confidentiality of Medical Information Act (CMIA, see 13) through 15) of Existing Law below).

15) Requires UCOP to submit a UC System Research Readiness Certification identifying the emerging therapies research capacity of the UC system to CalHHS, the Department of Finance (DOF), and the Legislature no later than 45 days after the operative date of this bill.

16) Requires the certification to include, for each relevant UC campus, including, at a minimum, UC San Francisco, UC San Diego, UC Los Angeles, UC Berkeley, and UC Davis, all of the following:

    a) A list of all active or pending federally registered clinical trials in emerging therapies, including the applicable investigational new drug (IND) or protocol number, the sponsoring faculty investigator, the trial phase, current enrollment status, and estimated completion date;

    b) A description of the campus institutional review board (IRB) infrastructure, including the IRB's experience with Schedule I substance research protocols;

    c) An assessment of the campus's patient recruitment infrastructure and capacity to enroll veterans, first responders, and other priority populations in emerging therapies clinical trials;

    d) An identification of existing research partnerships with USVA medical centers affiliated with, or proximate to, the campus; and

    e) An assessment of data infrastructure capacity to support deidentified outcome data sharing with state and federal agencies.

17) Requires UCOP to consult with UC campus research administrations, the UC Academic Senate, and the UC Health system in preparing the certification. Requires the certification to be transmitted to CalHHS and incorporated by reference into California's ARPA-H partnership application.

18) Requires CalVet to convene the Council no later than 90 days after the operative date of this bill. Requires the Council to include, at minimum, all of the following members:

    a) The Secretary of Veterans Affairs, or their designee, who shall serve as cochair;

    b) A UC faculty researcher with active emerging therapies clinical trial experience, appointed by UCOP, who shall serve as cochair;

    c) One representative from each of at least three California-based veterans service organizations, appointed by the Secretary of Veterans Affairs;

    d) A licensed physician with clinical experience in psychedelic-assisted therapy, appointed by the DHCS Director;

    e) A representative of the USVA Northern California Health Care System or the USVA Southern California Health Care System, appointed by CalVet in coordination with USVA;

    f) A representative of DHCS;

    g) A representative of the State Department of Public Health (DPH); and

    h) At least two members with lived experience as veterans who have accessed emerging therapies treatment, appointed by the Secretary of Veterans Affairs.

19) Requires Council members to serve without compensation.

20) Requires CalVet to provide administrative staffing for the Council from existing appropriations.

21) Requires the Council to do all of the following:

    a) Serve as the primary advisory body to CalVet, DHCS, and CalHHS on matters relating to emerging therapies research for veterans and other priority populations;

    b) Advise on veteran patient recruitment strategies and enrollment pipelines for UC-anchored clinical trials;

    c) Develop guidance on culturally appropriate and trauma-informed protocols for veteran participation in emerging therapies research;

    d) Recommend priority conditions and populations for emerging therapies research, including post-traumatic stress disorder (PTSD), treatment-resistant depression, opioid use disorder, and traumatic brain injury; and,

    e) Advise on the content of the federal readiness report.

22) Requires the Council to submit a California Veteran Emerging Therapies Research Needs Assessment to CalVet, CalHHS, and the Legislature no later than 180 days after the operative date of this bill. Requires the assessment to identify veteran mental health and substance use treatment gaps addressable through emerging therapies research and to serve as a supporting document for California's federal partnership application.

23) Requires CalHHS to submit, no later than January 1, 2028, a federal readiness report to the Legislature and DOF that addresses, at minimum, all of the following:

    a) The status of California's ARPA-H partnership designation application, including the date of submission, a federal agency response, if any, and the current designation status;

    b) The status of each data-sharing MOU required by this bill, including execution date and scope;

    c) The total amount of federal moneys received by the state or directly by UC campuses pursuant to this bill;

    d) The number of active federally registered emerging therapies clinical trials at UC campuses, the total enrolled participants, and the number of enrolled veteran participants; and,

    e) Recommendations for statutory or regulatory changes necessary to maintain or expand California's federal partnership eligibility.

24) States the provisions of this bill do not do any of the following:

    a) Appropriate GF moneys;

    b) Amend, repeal, or supersede any provision of 16) of Existing Law below. States that the possession, cultivation, distribution, or administration of a controlled substance outside of a federally registered clinical trial remains subject to applicable state and federal law;

    c) Create a therapeutic access program, a personal use exemption, or a regulatory licensing framework for the provision of emerging therapies to the general public; or

    d) Guarantee federal partnership designation or the receipt of federal moneys.

25) Defines "emerging therapies" to mean psilocybin, ibogaine, MDMA, dimethyltryptamine, and ketamine when used in the context of a federally registered clinical trial conducted under an IND application that is approved by the FDA.

26) Defines "federally registered clinical trial" to mean a clinical research study registered with ClinicalTrials.gov conducted pursuant to an FDA-approved, a research exemption pursuant to 17) of Existing Law below, or an equivalent federal authorization.

27) States that the provisions of this bill are severable and if any provision of this bill or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

28) Makes Legislative findings and declarations regarding federal funding, prior vetoed and chaptered legislation, and veteran suicide.

EXISTING LAW:

1) Establishes the Research Advisory Panel – California (RAPC) as an independent panel to encourage further research into the nature and effects of cannabis and hallucinogenic drugs and to coordinate research efforts on such subjects. [Health & Safety Code (HSC) § 11480]

2) Requires RAPC to review, and permits RAPC to approve, research projects to be conducted in this state that would require the administration of Schedule I or Schedule II controlled substances. Permits RAPC to review projects on an expedited basis and without the vote of the whole panel, until January 1, 2028, if the completed research application meets the following requirements:

   a) For all research projects, proof of independent peer review of the study for scientific merit and rigor by the National Institutes of Health, the United States Department of Defense, the Heffter Research Institute, the United States National Science Foundation, or a comparable group within an institutional setting that has previous experience with research or grant review.

   b) For all research projects, if otherwise required by law, one of the following: a Schedule I or II research registration issued by the United States Drug Enforcement Administration (DEA), an approval from the DEA for a research registration that is conditional on the approval of RAPC, or a copy of the application for a research registration submitted to the DEA, accompanied by a written acknowledgment of receipt of the application, or other evidence of authorization to conduct the research project pursuant to the federal Controlled Substances Act.

   c) For research projects involving human subjects:

      i) If approval by the FDA of an IND application is otherwise required by law, a letter from the FDA approving the application for an IND, a letter from the FDA indicating that the study may proceed, documentation that the 30-day statutory period for the FDA to respond to a project's submission of an application for approval of an IND has expired, or a signed copy of FDA IND application.

      ii) An approval letter from a federally chartered IRB of all study documents demonstrating that the board has considered relevant federal and state laws regarding the use of human subjects.

   d) For research projects with animal subjects: an approval letter from an institutional animal care and use committee (IACUC) established pursuant to federal law of all study documents demonstrating that the IACUC has considered relevant federal and state laws regarding for the use of live, vertebrate animals in the research project, and their humane treatment in compliance with all applicable state and federal regulations. [HSC § 11480.1]

3) Requires RAPC to annually, and in the manner determined by RAPC, report to the Legislature and the Governor those research projects approved by RAPC, the nature of each research project, and where available, the conclusions of the research project. [HSC § 11481]

4) Permits people who are entitled to use Schedule I, II, or both, controlled substances for the purpose of research, instruction, or analysis, to lawfully obtain and use those substances upon approval by RAPC in bona fide research, instruction, or analysis. [HSC § 11213]

5) Permits the Attorney General (AG), with the approval of RAPC, to authorize persons engaged in research on the use and effects of controlled substances to withhold the names and other identifying characteristics of individuals who are the subjects of the research, and prohibits them from being compelled in any civil, criminal, administrative, legislative, or other proceedings to identify the individuals who are the subjects of research for which the authorization was obtained. [HSC § 11603]

6) Permits the AG, with the approval of RAPC, to authorize the possession and distribution of controlled substances by persons engaged in research and exempts those persons from state prosecution for possession and distribution of controlled substances to the extent of the authorization. [HSC § 11604]

7) Establishes the experimental subjects bill of rights. [HSC § 24172]

8) Requires that experimental subjects provide their informed consent, voluntarily and freely given, prior to any medical experiment being undertaken. Defines "informed consent" to include, but not be limited to, being provided both verbally and in the written consent form, in nontechnical terms and in a language the subject is fluent in, a number of enumerated facts regarding the proposed experiment, which might influence the decision to undergo the experiment. [HSC § 24173]

9) Exempts from state informed consent requirements any person who is conducting a medical experiment as an investigator within an institution that holds an assurance with HHS pursuant to Part 46 of Title 45 of the Code of Federal Regulations and who obtains informed consent in the method and manner required by those regulations. [HSC § 24178]

10) Defines Schedule I-V drugs for the purposes of state law. [HSC § 11053, *et seq*.]

11) Establishes HIPAA, which provides privacy protections for patients' protected health information and generally prohibits a covered entity, as defined (health plan, health care provider, and health care clearing house), from using or disclosing protected health information except as specified or as authorized by the patient in writing. [45 Code of Federal Regulations (CFR) § 164.500, *et seq*.]

12) Provides that if HIPAA's provisions conflict with a provision of state law, the provision that is the most protective of patient privacy prevails. [45 CFR § 164.500, *et seq*.]

13) Establishes the CMIA, which establishes protections for the use of medical information. [Civil Code (CIV) § 56, *et seq*.]

14) Prohibits providers of health care, health care service plans, or contractors, as defined, from sharing medical information without the patient's written authorization, subject to certain exceptions. [CIV § 56.10.]

15) Provides that every provider of health care, health care service plan, pharmaceutical company, or contractor who creates, maintains, preserves, stores, abandons, destroys, or disposes of medical information shall do so in a manner that preserves the confidentiality of the information contained therein. Requires any provider of health care, health care service plan, pharmaceutical company, or contractor who negligently creates, maintains, preserves, stores, abandons, destroys, or disposes of medical information to be subject to remedies and penalties, as specified. [CIV § 56.101]

16) Regulates and penalizes the possession, manufacturing, distribution, and prescription of drugs through the California Uniform Controlled Substances Act. [Penal Code § 11000, *et seq.*]

17) Specifies the categories of clinical investigations that are exempt from the requirement for prospective IRB review under FDA regulations:

    a) Any investigation which commenced before July 27, 1981 and was subject to requirements for IRB review under FDA regulations before that date, provided that the investigation remains subject to review of an IRB which meets the FDA requirements in effect before July 27, 1981;

    b) Any investigation commenced before July 27, 1981 and was not otherwise subject to requirements for IRB review under FDA regulations before that date;

    c) Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review; and,

    d) Taste and food quality evaluations and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical, or environmental contaminant at or below the level found to be safe, by the FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. [21 CFR § 56.104]

FISCAL EFFECT: Unknown. As recently amended, this bill has not been analyzed by a fiscal committee.

COMMENTS:

1) **PURPOSE OF THIS BILL**. According to the author, every year, more than 6,000 veterans take their own lives —at a rate twice that of the civilian population. Too many of them never find relief, even after exhausting every standard treatment available to them. The author argues that we owe them more than sympathy. We owe them serious research into every promising option that might help. California already has that research underway. Our UC system runs more federally-registered clinical trials on emerging therapies than any public university system in the country — built through faculty expertise, philanthropic investment,

and years of institutional commitment, without a single dollar from the state budget. The federal government has now put $50 million on the table specifically for states ready to partner on this work. California isn't ready, on paper, to receive it. The author contends this bill fixes that, and it asks for nothing in return. It doesn't spend state money. It doesn't touch California's controlled substances laws. It doesn't create a new program for public access to any substance. What it does is simple: it directs our state agencies to formally apply for the federal partnership, asks the UC to document the research capacity it already has, and brings veterans' advocates to the table to help guide that work. The author concludes, that's the entire bill — an application, a certification, and an advisory council.

2) **BACKGROUND**.

a) **Veteran mental health**. According to a 2025 National Veteran Suicide Prevention Annual Report, Veterans make up 13% of the suicides in the nation. There were an estimated 47,711 suicides among all U.S. adults in 2023, on average 130.7 suicides per day. This includes 17.5 veteran suicides per day. Among Veterans in Veterans Health Administration (VHA) care who died from suicide in 2023, 60.9% had a VHA mental health or substance use disorder diagnosis, and 39.1% did not. According to USVA National Center for PTSD, PTSD is slightly more common among veterans than civilians. At some point in their life, 7% of veterans will have PTSD. In the general population, 6% will have PTSD in their lifetime. PTSD is also more common among female veterans at 13% versus male veterans at 6%. Research is ongoing to better understand how PTSD affects veterans of color, LGBTQ+ veterans, and those of other diverse backgrounds. These social factors impact risk of trauma and PTSD in civilian life and in the military. Additionally, the number of veterans with PTSD varies by service era.

b) **Current research efforts**. In December 2024 the USVA announced that it will fund a study on Methylenedioxymethamphetamine-assisted, or MDMA-assisted, therapy for PTSD and alcohol use disorder (AUD) among Veterans. This is the first USVA-funded study for psychedelic-assisted therapy since the 1960s. USVA researchers affiliated with Brown University and Yale University will evaluate the potential of MDMA-assisted therapy as a treatment option for veterans with both PTSD and AUD. Participants will receive psychotherapy sessions enhanced by MDMA, a psychedelic compound believed to increase emotional openness, reduce fear, and promote introspection during therapy. Some participants will be randomly chosen to receive an active placebo, which will be a lower dose of MDMA. The study is scheduled to take place at the Providence VA Medical Center in Rhode Island and the West Haven VA Medical Center in Connecticut and is anticipated to begin enrollment in fiscal year 2025. The grant award is approximately $1.5 million over five years. As with all USVA studies, treatments will be conducted in a clinical setting with strict safety protocols and following all appropriate federal guidelines for conducting studies with controlled substances. Pharmaceutical-grade MDMA will be used, and participants will be closely monitored to ensure their well-being throughout the study. Several military-focused news websites reported in 2025 that the studies would be expanding to nine additional sites in the Bronx, Los Angeles, Omaha, Palo Alto, Portland (Oregon), San Diego, San Francisco, West Haven, and White River Junction. Military.com states that each site will recruit participants based on specific diagnostic criteria and treatment history. Some trials focus on combat-

related PTSD, while others include veterans with depression or generalized anxiety disorder who have not responded to standard therapies.

Psilocybin Intervention for Veterans Overcoming Treatment-Resistant Depression (PIVOT) is a multi-site randomized controlled trial to evaluate the efficacy and risks of psilocybin for the treatment of depression in U.S. military veterans with and without concurrent PTSD. The study is estimated to start on June 1, 2026. Current studies involving veterans and controlled substances identify exclusion criteria, which make participants ineligible for the study. For example, the PIVOT study excludes participants with any of the following (non-exhaustive): lifetime bipolar, schizophrenia spectrum, or other psychotic disorders; first-degree relative with history of bipolar I, schizophrenia spectrum or other psychotic disorder; certain substance use disorders or use of psilocybin, ayahuasca, or other psychedelics within past six months; history of severe traumatic brain injury; diagnosis of dementia or related progressive neurocognitive disorder; suicidal ideation; psychiatric inpatient treatment within past three months of baseline; clinically significant hypertension.

c) **ARPA-H and April 2026 Executive Order (EO).** ARPA-H was established by Congress in 2022 under the Biden administration. However, President Trump has recently announced significant new funding directives and a major pivot in the agency's focus. On April 18, 2026, President Trump signed an EO aimed at accelerating treatments for severe mental illness, with a specific focus on veterans and treatment-resistant conditions. The order directs ARPA-H to allocate $50 million to match state government investments in clinical research for psychedelic therapies, including compounds like ibogaine. Specifically, the order directs the funds "to support and partner with State governments that have enacted or are developing programs to advance psychedelic drugs for serious mental illnesses, including through Federal funding, technical assistance, and data sharing as appropriate and consistent with applicable law." Last year, the Texas state legislature enacted a law allocating major state funding, reported as $50 million to $100 million, specifically to conduct clinical trials on ibogaine for veterans suffering from severe PTSD and traumatic brain injuries. Texas structured this legislation so that the state money could only be deployed if it was matched by outside investments. Initially, Texas lawmakers hoped that private investors or philanthropic donors would step up to provide the matching funds. When that private money was slow to materialize, the Trump administration's EO stepped in. Texas is currently the only state positioned to immediately apply for and absorb the bulk of this $50 million matching fund.

d) **RAPC.** Research entities seeking to conduct research projects concerning cannabis or hallucinogenic drugs in California must submit their research proposals to RAPC prior to receiving a DEA license to use controlled substances in a research project. These researchers are affiliated with public and private research universities, as well as private pharmaceutical companies and drug manufacturers. RAPC evaluates the scientific validity of each proposed project, and may reject proposals where the research is poorly conceived, would produce conclusions of little scientific value, or would not justify the exposure of human subjects in California to the risk of the proposed controlled substance exposure. Members of the panel are experts in their fields, and are appointed by the Governor, DPH, the State Board of Pharmacy, UC, a statewide professional medical society, a private medical university, and the AG. The California Department of Justice (DOJ) provides administrative and legal support to the RAPC. RAPC's work

complements a regulatory approval process that includes IRBs, the FDA, and DEA review of controlled substance research studies using Schedule I and II controlled substances, or that involve new treatments for misuse of substances, such as fentanyl and other opioids. While the FDA and DEA are government institutions, IRBs are institutional entities registered with the FDA and charged with providing ethical oversight of research involving human subjects.

e) **Scientific review of research proposals.** Research proposals are reviewed by several entities before they are ultimately approved. The steps in this approval process can vary based on the subject of the research. Human subjects, animal subjects, and In-Vitro studies dealing with Schedule I and II controlled substances in California are all approved by their funder, the DEA, and RAPC at a minimum. Research on human subjects must also be approved by an IRB. In practice, all of these approvals and reviews happen before the proposal is reviewed by RAPC. Following RAPC approval, the study is then subject to continuous monitoring by the IRB, DEA, FDA, and RAPC.

   i) **FDA.** For clinical drug trials, the FDA requires an IND application, which is a request for authorization from the FDA to administer an investigational drug or biological product to humans. The FDA defines a clinical investigation as any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. An experiment is any use of a drug except for the use of a marketed drug in the course of medical practice. The sponsor is any person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual of a pharmaceutical company, government agency, academic institution, private organization, or other organization.

      The FDA is responsible for reviewing the pre-clinical pharmacology and toxicology, chemistry and manufacturing, and previous human data (if available) under an IND application. The FDA has two primary objectives in reviewing an IND: 1) to assure the safety and rights of subjects in all phases of an investigation, and 2) to help assure that the quality of the scientific evaluation of the drug is adequate to permit an evaluation of the drug's effectiveness and safety in phases two and three studies.

   ii) **DEA.** For pharmaceutical controlled substances, the DEA's responsibility is twofold: to prevent diversion and abuse of these substances while ensuring an adequate and uninterrupted supply is available to meet the country's legitimate medical, scientific, and research needs. The DEA works closely with state and local authorities and other federal agencies to carry out this responsibility. According to the DEA, there are two separate categories for researcher registration which are based on controlled substance schedules: a schedule I researcher and a schedule II-V researcher. If a researcher wishes to conduct research in schedules I and schedules II-V, they must obtain two separate registrations. The DEA may require a state license to conduct research and/or a state-controlled substance registration, if applicable, to be obtained before issuing a federal registration.

      A schedule I research protocol must include the name, address, and DEA registration number of the investigator, as well as their institution or company and their qualifications. The protocol must also include the purpose of the research project, the controlled substances involved, including the amount needed (with justification) and

the source, a detailed description of the research procedures, the dosages to be administered, the method of administration, the location of the study, a statement of security provisions for handling the substances, and a manufacturing or import statement.

iii) **IRB**. According to UC, IRBs are administrative committees designated to provide ethical and regulatory oversight of research that involves human subjects. IRBs exist to protect the rights, safety, and welfare of human subjects involved in research projects, consistent with ethical principles and federal, state, and local regulations. IRBs are enacted under federal regulation (Part 46 of Title 45 of the Code of Federal Regulations) and are regulated by the Office for Human Research Protections within HHS.

3) **SUPPORT**. VetFund Foundation supports this bill stating that every year, more than 6,000 veterans nationwide die by suicide — at a rate roughly twice that of the civilian population. Many of these men and women have already exhausted the standard treatments available to them without finding relief. VetFund contends that the UC system already runs more federally registered clinical trials on emerging therapies than any other public university system in the country, built through years of institutional investment and philanthropic support, entirely without state dollars. On April 18, 2026, the federal government made $50 million available through ARPA-H for states to partner on this research. VetFund argues that California currently has no statutory mechanism to apply for that funding and this bill fixes that gap responsibly. The bill creates no new GF spending and does not alter California's controlled substances laws, create a therapeutic access program, or authorize personal use of any substance in any way. VetFund concludes this bill is simply a research infrastructure bill — directing our state agencies to apply for funding that is already on the table, certifying the research capacity the UC has already built, and bringing veterans' voices into that process through the bill's Veteran Emerging Therapies Research Advisory Council.

4) **DOUBLE REFERRAL**. This bill has been double referred; upon passage in this committee, it will be referred to the Assembly Military and Veterans Affairs Committee.

5) **RELATED LEGISLATION**.

a) AB 1616 (Davies) would require CalVet to establish a program to fund a study for nonnarcotic PTSD treatments and to submit a report that summarizes the findings and recommendations of the study to the Legislature no later than June 30, 2030. Would repeal the provisions on January 1, 2031. AB 1616 was held on the Assembly Appropriations Committee’s suspense file.

b) AB 2489 (Lowenthal) establishes, until January 1, 2032, the California Veterans’ Right to Try Act. Authorizes RAPC to submit one or more IND applications to the FDA for approval of a multisite clinical trial of psilocybin, ibogaine, or other Schedule I or Schedule II controlled substances, among a patient pool composed exclusively of veterans with conditions associated with suicidality among veterans. AB 2489 was held on the Assembly Appropriation Committee’s suspense file.

6) PREVIOUS LEGISLATION.

a) AB 1103 (Ward), Chapter 571, Statutes of 2025, requires RAPC to review research projects that administer Schedule I and Schedule II controlled substances to human research subjects and authorizes RAPC to expedite the review of projects that have sought or received certain federal approvals and have proof of independent peer review of the study, which would include authority of the chairperson to assign two or more panel members to review the research project and to approve it, without a vote by the entire panel. Extends the existing Bagley-Keene exemption to, and sunsets the expedited review process, January 1, 2028.

b) SB 751 (Becker) of 2025 would have requested the UC to establish local pilots to allow for the research and development of psilocybin services for veterans and former first responders, as specified. SB 751 was held on the Senate Appropriations Committee suspense file.

c) SB 803 (Becker) of 2024 would have created the Heal our Heroes Act which establishes the Psychedelic-Assisted Facilitation Pilot Program in the City and County of San Francisco, the County of San Diego, and the County of Santa Cruz. SB 803 died in the Assembly Health Committee.

d) SB 1012 (Wiener) of 2024 would have established the Regulated Psychedelic Facilitators Act and Regulated Psychedelic-Assisted Therapy Act, to be administered by three new state entities: a Division of Regulated Psychedelic-Assisted Therapy, a Board of Regulated Psychedelic Facilitators, and a Regulated Psychedelic Substances Oversight Committee. SB 1012 was held on the Senate Appropriations Committee suspense file.

e) SB 58 (Wiener) of 2023 would have made lawful the possession, preparation, obtaining, or transportation of specified quantities of psilocybin, psilocyn, dimethyltryptamine (DMT), and mescaline, for personal use, as defined, by persons 21 years of age or older. SB 58 was vetoed by Governor Newsom. The veto message stated, in part:

"California should immediately begin work to set up regulated treatment guidelines - replete with dosing information, therapeutic guidelines, rules to prevent against exploitation during guided treatments, and medical clearance of no underlying psychoses. Unfortunately, this bill would decriminalize possession prior to these guidelines going into place, and I cannot sign it. I urge the legislature to send me legislation next year that includes therapeutic guidelines. I am, additionally, committed to working with the legislature and sponsors of this bill to craft legislation that would authorize permissible uses and consider a framework for potential broader decriminalization in the future, once the impacts, dosing, best practice, and safety guardrails are thoroughly contemplated and put in place."

f) SB 519 (Wiener) of 2022 would have required DPH to convene a working group to research and make recommendations to the Legislature regarding the regulation and use of psilocybin, psilocyn, DMT, ibogaine, lysergic acid diethylamide, MDMA, and mescaline. SB 519 died on the Assembly Floor without a vote.

7) POLICY COMMENTS.

a) Short timelines. This bill is an attempt to be responsive to the April 2026 EO from President Trump, so many of the timelines in the bill are very short. Given that this bill was amended into this form on June 11, it is unclear what level of outreach and collaboration has happened with CalVet, CalHHS, DHCS, and UCOP. Should this bill move forward, the author should engage with all of these state partners to ensure that the requirements of the bill are feasible. Further, the author may wish to explore the possibility of adding an urgency clause in order for this bill to take effect immediately if it would allow the implementing entities to be eligible for federal funds.

b) Conflicts of interest. This bill requires CalVet to convene the Council to act as the advisory body on the emerging therapies research. This includes one faculty researcher with active emerging therapies clinical trial experience and a licensed physician with clinical experience in psychedelic-assisted therapy. This is valuable experience to have on this Council, and while the Council does not have any approval authority over research projects, the author may wish to consider if there are any possible conflicts of interest if a researcher or clinician on the Council is developing official guidance and protocols for research they may be conducting or advising themselves.

c) Is this bill necessary? Background provided by the author states that existing law provides no mechanism for the state to apply for the federal designation, no fund to receive the dollars, and no certified state record of California's existing research infrastructure. Should this bill move forward, the author may wish to engage with the relevant state partners, as noted in Comment a) to confirm that these mechanisms are required in order to receive these federal funds and whether legislation is necessary to put them in place.

REGISTERED SUPPORT / OPPOSITION:

Support

VetFund Foundation

Opposition

None on file

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